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SUBJECT: FRENCH BIOTECH AUTHORITY CREATED AS ECJ FINES FRANCE

Ref: (A) Paris 714; (B) Paris 1071; (C) Paris 2046

¶1. Summary: On December 7, France announced the creation of a new biotech evaluation authority in the French Official Journal. The declaration of the new "competent authority," called The High Biotech Committee, preceded, but did not halt, the imposition of a 10 million euro fine by the European Court of Justice (ECJ) for France's failure to implement European rules on growing genetically engineered crops. The creation of the authority will allow France to implement its biotech law, adopted in June 2008. However, the Committee, which will include a strong social and ethical component, is unlikely to be friendly to biotech cultivation. End Summary.

¶2. The establishment of a new biotech authority was a requirement of a French biotech law adopted in June, 2008. (refs A and B) The new law was prompted by a national environmental review in 2007 (which resulted in the dissolution of the previous, science-based competent authority) and by the fact that France faced significant fines for failure to enact a biotech framework in accordance with a 2002 EU law.

¶3. According to decree 2008-1273 published in the Journal, the new authority will broaden its evaluation of biotechnology approvals beyond science to include a socio-economic aspect as well. The authority will have two subcommittees, one supposedly focused on scientific analysis and the other on economic, ethical and social dynamics of biotechnology.

¶4. The scientific subcommittee will consist of a maximum of 40 members, including at least: 3 genetics specialists; 3 microbiology specialists; 10 specialists in human and animal health protection; 3 specialists in agronomy; one specialist in statistics; 3 specialists in environmental sciences; one lawyer; one economist; and one sociologist.

¶5. The economic, ethical and social subcommittee will consist of at least: one member of the national ethics consultative committee; 3 representatives from environmental protection organizations; 2 representatives from consumer organizations, one representative from the High Committee on Public Health; one representative from the hospital or public health sector; 5 representatives from farmers organizations; one representative from a food industry organization; one representative from the pharmaceutical industry organization; one representative from a seed industry organization; 2 representatives from biotech company employees organizations; one representative from the French mayor's organization; one

representative from the French administrative department organization; one representative from the French administrative region organization; one Parliamentarian from the Parliament's Science and Technology Office; one lawyer; one economist; and one sociologist.

¶16. The French Prime Minister's office has made a public call for nominations to the Committee and will choose the members. Members will serve five year terms. Ministers from Environment, Consumption, and Agriculture can request biotech evaluations from the new High Biotech Committee.

¶17. Following its implementation, the new Committee must resolve several pending items in order to implement the biotech bill adopted in June 2008 and come into compliance with EU requirements. These items include defining non-biotech products and establishing coexistence measures for biotech and non-biotech cultivation. In addition, the Committee must review pending dossiers on the confined use of genetically engineered (GE) products (the previous French committee used to review approximately 400 dossiers per year) and the release into the environment (cultivation) of a large number of GE products. Biotech companies in France are eager to resume open field trials in 2009 as no new trials were authorized in 2008.

¶18. Despite France's recent progress in establishing a biotech framework for genetically engineered crops, the European Court of Justice imposed a 10 million euro fine on France on December 9th for its failure to do so between 2002 and 2008. The Court rejected France's argument that it had been unable to enact the 2002 EU law requiring rules for biotech crop cultivation due to fervent anti-GMO activities in France. The Court called France's conduct "unlawful" and said the ruling should warn other Member States that failure to implement EU regulations comes with a price.

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¶19. Comment: Given the heavy workload of the Committee and its complex structure, the decision making process is expected to be lengthy and the expectation for new GE crop approval low. Following a freeze on the cultivation of GE corn in France in 2007, (ref C) the creation of this new Committee is not expected to result in a resumption of commercial production of GE crops in 2009. Moreover, the fact that even the so-called scientific committee includes a lawyer, an economist and a sociologist indicates that deliberations within the Committees will likely be contentious and it will be difficult for the authority as a whole to find a way forward. End Comment.

Pekala